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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER

NASHED, NASHAAT T

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/25/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/825,212

Applicant(s)

BENSON, TIMOTHY E.

Examiner

Nashaat T. Nashed, Ph. D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 March 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 47-62 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 47-62 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to..
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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The application has been amended as requested in the communication filed March 22, 2005. Accordingly, claims 1-46 have been canceled, claims 47, 52, and 53 have been amended, and new claims 54-62 have been entered.

In response to the objection to the specification for improper use of trademark names, applicant has amended the specification by capitalizing the trademark names. Applicants, however, is not completely responsive to the objection because they have not provided the generic terminology for the trade names. Specifically, conditions 4, 16, 29, 33, and 38 of HAMPTON CRYSTAL SCREEN I, and 6, 14, 18, 29, 34, and 36 of WIZARD SCREEN I are not defined by their generic chemical composition.

New corrected drawings in compliance with 37 CFR 1.121(d) are required in this application because Figures 6a-6d are incomprehensible and do not show what is intended to be shown. Applicant is advised to employ the services of a competent patent draftsman outside the Office, as the U.S. Patent and Trademark Office no longer prepares new drawings. The corrected drawings are required in reply to the Office action to avoid abandonment of the application. The requirement for corrected drawings will not be held in abeyance.

Applicant is not responsive to the above objection to the drawing. The examiner acknowledge that the Office had received the drawing filed January 29, 2002 and February 25, 2002, which have been examined and objected to in the prior Office action.

This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 because the specification contains reference to specific amino acid residues not identified by a sequence identification number and the *S. aureus* is not identified by a sequence identification number at each mentioning of the protein. Applicant is required to perfect their compliance with the sequence rules.

Applicant made a serious attempt to perfect their compliance with the sequence rule, but his effort fail short. Table 1 for example, which discloses SEQ IID NO: 1 does not indicate the sequence disclosed in the Table is that of SEQ ID NO: 1. Also, at page 38, line 10, applicant must insert SEQ ID NO: 1 following *S. aureus* thioredoxin reductase, see also page 5, line 6, and claims 48, 52, 53, and 54. The cited examples are not an exhaustive search for all non-compliance with the sequence rules. Applicant has the burden to identify all instances where compliance is required, and perfect his compliance with the sequence rule.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.

Claims 56-58 and 60-62 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation "wherein the three-dimensional configuration of the amino acid listed in Table". Such a limitation lacks sufficient antecedent basis in the claim from which the claims depend.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 55-62 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention (new matter rejections).

The specification does not describe a polypeptide consisting of amino acid sequence starting at amino acid sequence 10-12 and ending with amino acid residue 290-297 of SEQ ID NO: 1 (claims 55-58) or a polypeptide starting at residue 43-52 and ending at residues 286-289 of SEQ ID NO: 1 (new claims 59-62). Applicant alleges that Tables 2-4 at pages 5-7 describe new claims 55-62. The examiner disagrees. Table 2-4 lists the amino acid residues with 4, 7, and 10 Angstrom units, respectively, from the FDA binding site of thioredoxin reductase of SEQ ID NO: 1. Said Tables describe properties of the polypeptide of SEQ ID NO: 1 and not the polypeptide comprising the amino acid residues shown in the Tables. It should be noted that the properties listed in Tables 2-4 are those of the polypeptide of SEQ ID NO: 1 and there is no evidence in the application to suggest that the polypeptide fragments of claims 55-62 has the same intrinsic property as that of SEQ ID NO: 1. Given this lack of description of the claimed invention, Applicant has failed to sufficiently describe the claimed invention, in such full, clear, concise, and exact terms that a skilled artisan would recognize Applicants were in possession of the claimed invention. Applicant must delete the new matter from the claims.

Claims 47-54 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention for the reasons set forth in the prior Office action mailed October 19, 2004.

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New claim 54 is include because it's drawn to a poorly defined crystal comprising a polypeptide with undefined amino acid sequence.

Applicant has not responded to the rejection of record and indicated that the specification provides adequate written description for the claimed invention.

Applicant's arguments filed 3/16/05 have been fully considered, but they are found unpersuasive. Applicant allegedly describes the crystallization of the polypeptide of SEQ ID NO: 1 under conditions 4, 16, 29, 33, and 38 of HAMPTON CRYSTAL SCREEN I, and 6, 14, 18, 29, 34, and 36 of WIZARD SCREEN I which are not defined by their generic chemical composition. One of ordinary skill in the art would not know the cited conditions. Said conditions provided an orthorhombic crystal in the space group $P4_32_12$, $a = 70 \text{ \AA}$, $b = 70 \text{ \AA}$, and $c = 160 \text{ \AA}$, $\alpha = \beta = \gamma = 90^\circ$ of the polypeptide of SEQ ID NO: 1. No other crystal is described in the specification. Applicant is entitle for the specifically described crystal, when they introduce the generic chemical composition of said conditions and provide the adequate support that such an amendment does not include new matter. Also, applicant should note the atomic coordinates in Table 1 are those obtained for the said orthorhombic crystal described above. The method of claim 47 are directed to crystallization of any protein comprising SEQ ID NO: 1 under such a broad conditions: starting with a protein solution containing 1 mg/ml-50 mg/ml protein, from a solution having pH 6 to 10, 0%-40% DMSO, and 0.1-6 M sodium formate. Applicant does not describe adequate conditions to grow a crystal suitable for structure determination by X-ray crystallography. With regard to case 4 the trilateral report section A3, it states in that the specification teaches how to make the claimed crystal. The specification has failed to adequately teach how to make a crystal of any kind.

Claims 47-54 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement for the reasons set forth in the prior Office action mailed October 19, 2004.

In response to the above rejection, applicants argue:

"A specification disclosure which contains a teaching of the manner and process of making and using an invention in terms which correspond in scope to those used in describing and defining the subject matter sought to be patented must be taken as being in compliance with the enablement requirement of 35 U.S.C. 112, first paragraph, unless there is a reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support." M.P.E.P. 2164.04. "As long as the specification discloses at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim, then the enablement requirement of 35 U.S.C. 112 is satisfied."

M.P.E.P. 2164.01(b). "For a claimed genus, representative examples together with a statement applicable to the genus as a whole

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will ordinarily be sufficient if one skilled in the art (in view of level of skill, state of the art and the information in the specification) would expect the claimed genus could be used in that manner without undue experimentation. Proof of enablement will be required for other members of the claimed genus only where adequate reasons are advanced by the examiner to establish that a person skilled in the art could not use the genus as a whole without undue experimentation." M.P.E.P. 2164.02, paragraph entitled "WORKWG EXAMPLES AND A CLAIMED GENUS" (emphasis added). "[E]ven in unpredictable arts, a disclosure of every operable species is not required." M.P.E.P. 2164.03.

Applicants' arguments filed 3/16/05 have been fully considered but they are not deemed to be persuasive. Enablement requires a disclosure sufficient to allow a person of skill in the art to practice the full scope of the claimed invention without undue experimentation. The previous Office action sets out a *prima facie* case of non-enablement, explaining by sound scientific reasoning why a person of ordinary skill in the art would doubt that the guidance of the specification would enable practice of the full scope of the claimed invention without undue experimentation. Applicants have presented no evidence or, indeed, any arguments to establish the adequacy of the disclosure to enable the scope of the instant claims. Applicants merely quote the MEPE without much explanation why the scope of the claimed invention is enabled. Applicants make no effort to explain why they consider the disclosure of one specific crystal for the amino acid sequence of the fusion protein of SEQ ID NO: 1 and a partial method for its making to be enabling with respect to any crystal comprising a polypeptide of *S. aureus* thioredoxin reductase including any mutants thereof and fusion proteins thereof. Applicant should be reminded that protein crystallization is highly unpredictable and any change in the amino acid sequence or crystallization conditions would produce no crystal or crystals that are not suitable for structure determination by X-ray crystallography. Conclusory statements unsupported by evidence or scientific reasoning are insufficient to overcome the *prima facie* case of non-enablement set out in the previous Office action.

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

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extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nashaat T. Nashed, Ph. D. whose telephone number is 571-272-0934. The examiner can normally be reached on MTTF.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy can be reached on 571-272-0928. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Nashaat T. Nashed, Ph. D.
Primary Examiner
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